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DRUG ENFORCEMENT ADMINISTRATION

Additional Actions Needed to Address Prior GAO Recommendations

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GAO Highlights

Highlights of GAO-16-737T, a testimony before the Committee on the Judiciary, U.S. Senate

Why GAO Did This Study

DEA administers and enforces the CSA to help ensure the availability of controlled substances, including certain prescription drugs, for legitimate use while limiting their availability for abuse and diversion. The CSA requires DEA to set quotas that limit the amount of certain substances that are available in the United States. The CSA also requires those handling controlled substances to register with DEA. In addition, DEA works to disrupt and dismantle major drug trafficking organizations and uses confidential informants to help facilitate its investigative efforts.

This testimony addresses DEA's efforts to address prior GAO recommendations concerning: (1) administration of the quota process, (2) information provided to registrants on their roles and responsibilities under the CSA, and (3) compliance with guidelines regarding confidential informants. This statement is based on findings from three GAO reports issued during 2015, and selected status updates from DEA through June 2016. In its prior work, GAO analyzed quota data, surveyed DEA registrants, reviewed DEA policy documents and interviewed DEA officials. For selected updates, GAO reviewed DEA documentation and held discussions with agency officials.

What GAO Recommends

GAO previously made eleven recommendations to DEA related to the quota process, guidance to registrants, and confidential informants. DEA generally agreed with and has begun taking actions to address the recommendations, and has so far fully implemented two.

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June 22, 2016

DRUG ENFORCEMENT ADMINISTRATION

Additional Actions Needed to Address Prior GAO Recommendations

What GAO Found

In three reports issued during 2015, GAO made eleven recommendations to the Drug Enforcement Administration (DEA) related to administering the quota process for controlled substances, providing information and guidance to registrants, and complying with guidelines for overseeing confidential informants. As of June 2016, DEA had taken some actions to address these recommendations but had fully implemented only two of them.

Administering the quota process. In February 2015, GAO found that DEA had not effectively administered the quota process that limits the amount of certain controlled substances available for use in the United States. For example, manufacturers apply to DEA for quotas needed to make drugs annually. GAO found that DEA did not respond within the time frames required by its regulations for any year from 2001 through 2014, which, according to some manufacturers, caused or exacerbated shortages of drugs. GAO recommended that DEA take seven actions to improve its management of the quota process and to address drug shortages. In March 2015, DEA implemented one recommendation to finalize an information sharing agreement with the Food and Drug Administration regarding drug shortages. In June 2016, DEA implemented a second recommendation strengthening internal controls in the quota system. DEA has not fully implemented the other five recommendations. In October 2015, DEA identified steps it planned to take, including developing performance standards for responsiveness to manufacturers, but has not yet completed these actions.

Providing information to registrants. In June 2015, based on four nationally representative surveys of DEA registrants, GAO reported that many registrants were not aware of various DEA resources, such as manuals for pharmacists and practitioners. In addition, some distributors, individual pharmacies, and chain pharmacy corporate offices wanted improved guidance from, and additional communication with, DEA about their roles and responsibilities under the Controlled Substances Act (CSA). GAO recommended that DEA take three actions to increase registrants' awareness of DEA resources and to improve the information DEA provides to registrants. In April 2016, DEA reported that it had taken some steps towards addressing these recommendations, such as developing web-based training and updating the Pharmacist's Manual to reflect new regulations. However, DEA did not mention plans to develop and distribute additional guidance for distributors or pharmacies and therefore has not yet fully implemented GAO's recommendations.

Compliance with confidential informant guidelines. In September 2015, GAO reported that DEA's confidential informant policies were not fully consistent with provisions in the *Attorney General's Guidelines*. For example, DEA did not fully address the requirements to provide the informant with written instructions about authorized illegal activity and require signed acknowledgment from the informant. GAO recommended that DEA update its policy and corresponding monitoring processes to explicitly address these particular provisions in the Guidelines. According to an April 2016 memo and subsequent follow up, DEA has revised its policy accordingly, and it is undergoing internal processing, which is expected to be completed in summer 2016. Until GAO can review the new policy and verify that it complies with the Guidelines, this recommendation remains open.

Chairman Grassley, Ranking Member Leahy, and Members of the Committee:

I am pleased to be here today to discuss our past work examining specific activities related to the Drug Enforcement Administration's (DEA) efforts to prevent abuse and diversion of controlled substances and the agency's use of confidential informants.

The Centers for Disease Control and Prevention (CDC) has declared that the United States is in the midst of an epidemic of prescription drug overdose deaths. In 2013, more than 22,000 Americans died from drug overdoses attributable to prescription drugs, and most of those deaths—more than 16,000—were attributable to prescription opioid pain relievers. While these prescription drugs have legitimate purposes and are safe when taken as directed, they also can be misused, and pose a potential for abuse and addiction as well as being diverted for illicit uses.¹

Multiple federal agencies have responsibility for addressing the misuse, abuse, and diversion of prescription drugs through prevention, treatment, and enforcement activities. In particular, DEA has a key role as it enforces the Controlled Substances Act (CSA). The CSA was enacted in 1970 to regulate and facilitate the use of controlled substances, including certain prescription drugs such as opioid pain relievers, for legitimate medical, scientific, research, and industrial purposes while preventing

¹Diversion can occur in a variety of ways, including as a result of illegal or improper prescribing, prescription forgery, pharmacy thefts, or "doctor shopping" where an individual—who may or may not have legitimate medical needs—goes to several doctors to obtain a prescription from each doctor. Diversion can also occur through illegal sales of prescription drugs, such as drugs sold by physicians, patients, or pharmacists, as well as individuals obtaining these substances without a valid prescription through Internet pharmacies or pain clinics.

them from being diverted for illegal uses.² The CSA requires DEA to maintain a closed system of distribution, which includes limiting the amount of certain controlled substances that are available by setting quotas. Various CSA provisions also require persons who handle controlled substances to register with the DEA, including businesses that import, export, manufacture, or distribute controlled substances; health care practitioners, such as physicians, licensed to dispense, administer, or prescribe them; and pharmacies authorized to fill prescriptions.³ These DEA registrants have certain responsibilities under the CSA and its implementing regulations for preventing abuse and diversion of controlled substances.

As the nation's lead federal agency dedicated to drug law enforcement, DEA also works to disrupt and dismantle the leadership, command, control, and financial infrastructure of major drug-trafficking organizations. DEA uses confidential informants to help facilitate its investigative efforts, and the Attorney General has issued guidelines to help ensure appropriate oversight of informants.⁴

My testimony today summarizes DEA's progress addressing recommendations from our prior work on DEA's efforts to prevent abuse

²Pub. L. No. 91-513, tit. II, 84 Stat. 1236, 1242-84 (codified as amended at 21 U.S.C. §§ 801-890, 901-971). According to the CSA, the term "controlled substance" means "a drug or other substance, or immediate precursor, included [in one of five classification schedules.]" A controlled substance is placed in a respective schedule based on whether it has a currently accepted medical use in treatment in the United States and its relative abuse potential and likelihood of causing dependence. The order of the schedules reflects substances that are progressively less dangerous and addictive. The term "controlled substance" as used in this report includes controlled prescription drugs such as opioid pain relievers, as well as controlled bulk materials that are manufactured into controlled prescription drugs. For simplicity, in this report, we use the term "prescription drugs" to refer to controlled prescription drugs.

³Practitioners, as used throughout this report, includes both those who DEA categorizes as practitioners for the purposes of registration, such as physicians, dentists, and podiatrists, and those DEA categorizes as mid-level practitioners for the purposes of registration, such as nurse practitioners, nurse anesthetists, and physician assistants.

⁴The *Attorney General Guidelines Regarding the Use of Confidential Informants* defines a confidential informant as any individual who provides useful and credible information to a law enforcement agency regarding felonious criminal activities, and from whom the law enforcement agency expects or intends to obtain additional useful and credible information regarding such activities in the future.

and diversion of prescription drugs and to ensure accountability of confidential informants. Specifically, this testimony addresses key findings, recommendations, and DEA's efforts in three areas:

1. DEA's administration of the quota process for controlled substances, and its efforts to address drug shortages;
2. the extent to which DEA has provided information to its registrants regarding their roles and responsibilities for preventing abuse and diversion of controlled substances; and
3. the extent to which DEA's policies regarding the use of confidential informants is consistent with the Attorney General guidelines.

This statement is based on three reports related to DEA that we issued from February 2015 to September 2015, as well as information DEA provided from March 2015 through June 2016 on its progress in implementing recommendations from those reports.⁵ For our past work on DEA's administration of the quota process, we reviewed DEA's regulations and other agency documentation and analyzed data from a stratified random sample of 2011 and 2012 source documents from DEA's Year-End Reporting and Quota Management System (YERS/QMS), which is the official record for the quota process. We also interviewed officials from DEA, the Food and Drug Administration (FDA), organizations representing patients and providers, and drug manufacturers. For our prior work on DEA registrants, we administered nationally representative web-based surveys to DEA-registered distributors, individual pharmacies, chain pharmacy corporate offices, and practitioners. We also interviewed officials from DEA, 26 national associations and other nonprofits, and 16 government agencies in four states representing different geographic regions with varying overdose death rates. For our work on confidential informants, we reviewed DEA's and other federal law enforcement agencies' documented policies and monitoring processes and interviewed agency officials about their

⁵GAO, *Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should Be Improved*, GAO-15-202 (Washington, D.C.: Feb. 2, 2015); GAO, *Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access*, GAO-15-471 (Washington, D.C.: Jun. 25, 2015); GAO, *Confidential Informants: Updates to Policy and Additional Guidance Would Improve Oversight by DOJ and DHS Agencies*, GAO-15-807 (Washington, D.C.: Sept. 15, 2015).

practices. We also visited agencies' field offices in three locations chosen based on the numbers of informants overseen, among other factors. Further details on the scope and methodology for our previously issued reports are available within each published product. To determine DEA's progress in implementing the recommendations from our prior work, we reviewed DEA documentation and held follow up discussions with DEA and Department of Justice (DOJ) officials. We conducted the work on which this statement is based in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Quotas for Controlled Substances

DEA establishes quotas for the maximum amount of each basic class of schedule I and II controlled substances—such as amphetamine or morphine—that can be produced each year in the United States.⁶ DEA also establishes quotas for individual manufacturers, who must apply to DEA to obtain quotas for specific classes of controlled substances. The CSA and DEA's implementing regulations specify dates by which DEA must propose and establish its quotas. The quotas that DEA establishes each year are required to provide for the estimated medical, research, and industrial needs of the United States.⁷ In setting quotas, DEA considers information from many sources including manufacturers' production history and anticipated needs from manufacturers' quota applications and past histories of quota granted for each substance from

⁶Schedule I controlled substances, such as heroin and LSD, have a high potential for abuse and no currently accepted medical use in treatment in the United States, while schedule II controlled substances such as oxycodone have a high potential for abuse that may lead to severe psychological or physical dependence, but also have a currently accepted medical use. Quotas are not established for schedule III, IV, and V controlled substances, which have a currently accepted medical use, a lower potential for abuse, and a lower physical and psychological dependence relative to schedule I and II controlled substances.

⁷In addition, DEA is also required to provide for lawful export requirements, and for the establishment and maintenance of reserve stocks. 21 U.S.C. § 826; 21 C.F.R. § 1303.11.

YERS/QMS, which is DEA's system for tracking and recording quota applicants and decisions.

Both DEA and FDA have important responsibilities in preventing and responding to shortages of drugs containing controlled substances subject to quotas. In addition to preventing diversion, DEA works to ensure that an adequate and uninterrupted supply of controlled substances is available for legitimate medical and other needs. As part of its mission, FDA works to prevent, alleviate, and resolve drug shortages. The Food and Drug Administration Safety and Innovation Act (FDASIA), enacted in 2012, contains provisions that require DEA and FDA to coordinate their respective efforts during shortages of drugs containing controlled substances subject to quotas. When FDA is notified of a supply disruption of certain drugs that contain controlled substances subject to quotas, FDASIA requires that FDA request that DEA increase quotas applicable to that controlled substance, if FDA determines that it is necessary.⁸ Similarly, when FDA has determined that a drug subject to quotas is in shortage in the United States, manufacturers may submit quota applications requesting that DEA authorize additional quota for that substance. FDASIA requires that DEA respond to these requests from manufacturers within 30 days.⁹

DEA Registrants

The CSA requires businesses, entities, or individuals that import, export, manufacture, distribute, dispense, conduct research with respect to, or administer controlled substances to register with the DEA. As of December 2014, there were over 1.5 million registered distributors, pharmacies, and practitioners; more than 1.4 million of these registrants were practitioners.¹⁰

DEA registrants must comply with a variety of requirements imposed by the CSA and its implementing regulations. For example, a registrant must

⁸Pub. L. No. 112-144, § 1001, 126 Stat. at 1099-1100 (codified at 21 U.S.C. § 356c).

⁹Pub. L. No. 112-144, § 1005, 126 Stat. at 1105 (codified at 21 U.S.C. § 826(h)).

¹⁰There were more than 30,000 other types of entities registered with DEA, including, manufacturers, hospitals and clinics, importers/exporters of controlled substances, narcotic treatment programs, and researchers who use controlled substances or medications in their research or analyses.

keep accurate records and maintain inventories of controlled substances, among other requirements, in compliance with applicable federal and state laws. Additionally, all registrants must provide effective controls and procedures to guard against theft and diversion of controlled substances. Examples of some of the specific regulatory requirements for distributors, pharmacists, and practitioners include the following:

- **Distributors:** Registrants must design and operate a system to disclose suspicious orders of controlled substances, and must inform the DEA field division office in the registrant's area of suspicious orders when the registrant discovers them.¹¹
- **Pharmacists:** While the responsibility for proper prescribing and dispensing of controlled substances rests with the prescribing practitioner, the pharmacist who fills the prescription holds a corresponding responsibility for ensuring that the prescription was issued in the usual course of professional treatment for a legitimate purpose.¹²
- **Practitioners:** Practitioners are responsible for the proper prescribing and dispensing of controlled substances for legitimate medical uses. A prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of that person's professional practice.¹³

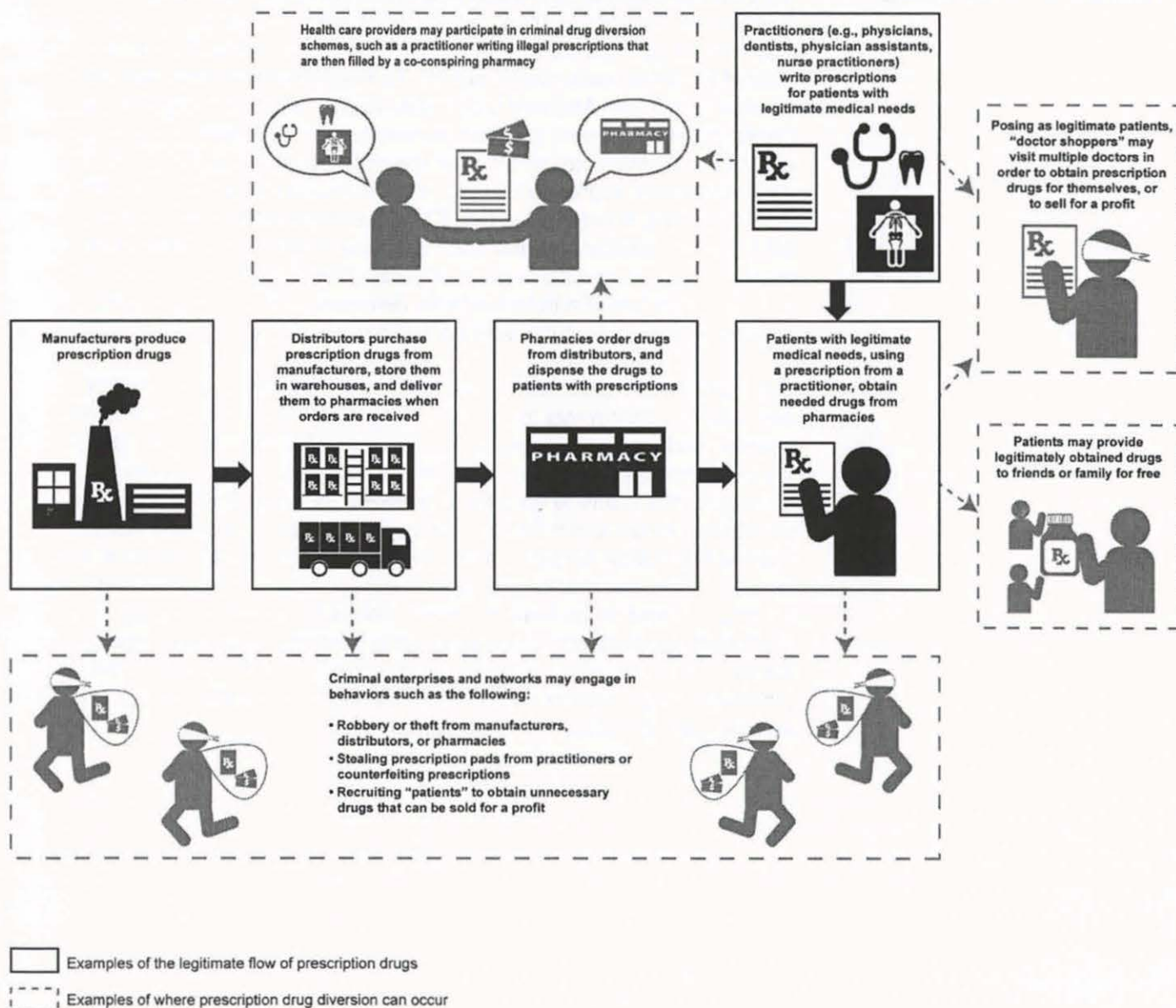
It is important for registrants to adhere to their responsibilities under the CSA because they play a critical role in the prescription drug supply chain, which is the means through which prescription drugs are ultimately delivered to patients with legitimate medical needs. Although prescription drugs are intended for legitimate medical uses, as shown in figure 1, the prescription drug supply chain may present opportunities for the drugs to be abused and diverted. For example, an individual may visit multiple practitioners posing as a legitimate patient, referred to as a doctor shopper, to obtain prescriptions for drugs for themselves or others. In an example of diversion, criminal enterprises may rob distributors and pharmacies of prescription drugs to sell to others for a profit.

¹¹ 21 C.F.R. § 1301.74(b).

¹² 21 C.F.R. § 1306.04(a).

¹³ 21 C.F.R. § 1306.04(a).

Figure 1: An Example of the Prescription Drug Supply Chain and Opportunities for Abuse and Diversion



Sources: GAO (data); GAO and Art Explosion (clipart). | GAO-16-737T

Confidential Informants

Confidential informants provide information and take action at the direction of law enforcement agencies to further investigations. Agencies may rely on confidential informants in situations in which it could be difficult to use an undercover officer. To help ensure appropriate oversight of informants, *The Attorney General's Guidelines Regarding the Use of Confidential Informants* (the Guidelines) set forth detailed procedures and review mechanisms to ensure that law enforcement agencies exercise their authorities appropriately and with adequate oversight. Adherence to the Guidelines is mandatory for DOJ law enforcement agencies, including DEA. The Guidelines require each DOJ law enforcement agency to develop agency-specific policies regarding the use of informants, and the DOJ Criminal Division is tasked with reviewing these agency-specific policies to ensure that the policies comply with the Guidelines.

The Guidelines require that, prior to using a person as an informant, agencies vet informants to assess their suitability for the work and that agents conduct a continuing suitability review for the informant at least annually thereafter. Additionally, the Guidelines permit agencies to authorize informants to engage in activities that would otherwise constitute crimes under federal, state, or local law if someone without such authorization engaged in these same activities. For example, in the appropriate circumstance, an agency could authorize an informant to purchase illegal drugs from someone who is the target of a drug-trafficking investigation. Such conduct is termed "otherwise illegal activity." The Guidelines include certain requirements for authorizing otherwise illegal activity and restrictions on the types of activities an agency can authorize.

DEA Has Taken Some Actions but Has Not Yet Implemented Most of GAO's Recommendations Regarding the Quota Process and Efforts to Address Drug Shortages

In our February 2015 report, we found that DEA had not effectively administered the quota process, nor had DEA and FDA established a sufficiently collaborative relationship to address shortages of drugs containing controlled substances subject to quotas.¹⁴ Since then, DEA has taken some actions to address the seven recommendations we made in our February 2015 report with respect to the agency's administration of the quota process and efforts to address drug shortages, but DEA has only fully implemented two of the seven recommendations.

DEA Had Not Effectively Administered the Quota Process Due to Missed Time Frames and a Lack of Internal Controls

As we reported in February 2015, DEA had not proposed or established quotas within the time frames required by its regulations for any year from 2001 through 2014.¹⁵ DEA officials attributed this lack of compliance to inadequate staffing and noted that the agency's workload with respect to quotas had increased substantially. Manufacturers who reported quota-related shortages cited late quota decisions as causing or exacerbating shortages of their drugs. We could not confirm whether DEA's lack of timeliness in establishing quotas had caused or exacerbated shortages because of concerns about the reliability of DEA's data, among other things. However, by not promptly responding to manufacturers' quota applications, we concluded that DEA may have hindered manufacturers' ability to manufacture drugs that contain schedule II controlled substances that may help prevent or resolve a shortage.

Additionally, our February 2015 report found that DEA had weak internal controls, which jeopardized the agency's ability to effectively manage the quota process. Specifically:

¹⁴GAO-15-202.

¹⁵We also found that DEA did not establish quotas from 2001 through 2013 according to the time frames required by the CSA, though it did meet this deadline for the 2014 quotas.

- DEA did not have adequate controls to ensure the reliability of YERS/QMS, which it used to track manufacturers' quota applications and record its quota decisions. DEA officials described some data checks of YERS/QMS, such as managers verifying that information entered into the system was accurate. However, the agency did not have systematic quality checks to ensure that the data were accurate or the checks it had in place were sufficient. This lack of systematic data checks was also concerning because we estimated that 44 percent of YERS/QMS records in 2011 and 10 percent in 2012 had errors. DEA officials said that 2011 was the first year manufacturers applied for quotas electronically and they expected data from 2012 and beyond to be more accurate.
- DEA lacked critical management information because it did not have performance measures related to setting quotas. In the absence of such performance measures, we concluded that DEA was missing important information for program managers to use when making decisions about program resources, and the agency could not effectively demonstrate program results.
- DEA did not monitor or analyze YERS/QMS data to assess the performance of the quota process. Absent such analysis, DEA was unable to evaluate its responses to manufacturers' quota applications or to understand the nature of its workload.
- DEA did not have reasonable assurance that the quotas it set were in accordance with its requirements and could not ensure continuity of its operations, as it did not have protocols, policies, training materials, or other documentation to manage the quota process. Instead, the agency said it relied on its regulations and the CSA to serve as guidance on how to conduct these activities. However, the need for detailed policies, procedures, and practices is particularly important because the process of setting quotas is very complex, requiring staff to weigh data from at least five different sources that may have contradictory information.

To address these deficiencies, our February 2015 report recommended that DEA take four actions to ensure it is best positioned to administer the quota process. Specifically, we recommended that DEA (1) strengthen its internal controls of YERS/QMS, (2) establish performance measures related to quotas, (3) monitor and analyze YERS/QMS data, and (4) develop internal policies for processing quota applications and setting quotas. In commenting on our report, DEA did not explicitly agree or disagree with these four recommendations.

As of June 2016, DEA has taken some actions to address these recommendations. Specifically, in response to our first recommendation, the agency stated that it implemented a series of system-generated flags in YERS/QMS that verify the information manufacturers enter into their quota applications and identify entries made by DEA staff that warrant further review within the agency. Additionally, in October 2015, DEA said that it would compare a random sample of manufacturers' applications and DEA's responses in YERS/QMS on a quarterly basis starting in fiscal year 2016. In June 2016, DEA provided the results of its review of 146 YERS/QMS records from March through May 2016, which identified a nearly nonexistent error rate (.01 percent). Because of these actions, we believe that DEA has implemented this recommendation.

In response to our second recommendation, DEA stated in October 2015 that it would develop performance standards that outline time frames for when manufacturers should expect DEA to respond to their quota applications, as well as develop web-based training to help manufacturers improve the quality of the information submitted to the agency. However, in June 2016, DEA stated that developing performance measures specific to the quota process would not be feasible because actions affecting quotas are outside of the agency's control. Instead, DEA focused on training manufacturers about the quota process to improve the accuracy and quality of their quota applications by holding additional trainings in April 2016 and developing web-based training. The agency plans to finish developing the web-based training in fiscal year 2017. Although training is an important step in improving the information being submitted to DEA, it is also important that DEA establish measures to assess its performance in achieving its mission of ensuring an adequate and uninterrupted supply of controlled substances, as it does for its diversion-related mission. As a result, we do not believe DEA's actions are fully responsive to our recommendation.

In response to our third recommendation, DEA stated that it streamlined its process for reviewing manufacturers' quota applications, which led to a significant reduction in the agency's response times. For example, DEA said that it is now responding to manufacturers' quota applications within four weeks. As of June 2016, the agency plans to continue monitoring and analyzing the quality of the YERS/QMS data and DEA's timeliness in responding to quota applications. We are currently awaiting documentation about DEA's analysis of YERS/QMS data in relation to the agency's timeliness in responding to manufacturers' quota applications and will update the status of this recommendation as applicable.

Lastly, in response to our fourth recommendation, in June 2016, DEA said that it established internal policies for the quota process and is in the process of updating its employee training materials for new staff to help ensure that each staff member has the information needed to issue quotas in accordance with the CSA and DEA's regulations. DEA agreed to provide the materials to us when they are completed, and we will assess the status of this recommendation at that time.

Lack of Effective Coordination May Hinder the Ability of DEA and FDA to Address Future Shortages of Drugs Containing Controlled Substances

Our February 2015 report also identified several barriers that may hinder DEA and FDA from effectively coordinating with each other during shortages of drugs containing controlled substances subject to quotas. For example:

- We found that DEA and FDA sometimes disagreed about what constitutes a shortage because the two agencies defined drug shortages differently. FDA defined a drug shortage as a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug.¹⁶ In contrast, DEA officials told us that there is no shortage, from DEA's perspective, as long as there is quota available to manufacture a given controlled substance, regardless of which particular manufacturers are producing the product and which strengths or formulations are available. We concluded that by not reaching agreement about what constitutes a drug shortage, it was unclear whether the two agencies would be able to successfully coordinate should a shortage of a drug containing a controlled substance subject to a quota occur.
- We also found that DEA lacked policies, procedures, or other means to coordinate with FDA about shortages of a controlled substance related to quotas. FDA established such policies and procedures in September 2014, but DEA officials said the agency did not plan to establish formal policies and procedures to coordinate the agency's response to FDA. While FDASIA directs DEA to respond within 30 days to manufacturers that request additional quota pertaining to a shortage of a schedule II drug, the law does not specify how quickly DEA must respond to a request from FDA. A time frame for DEA to respond would be particularly important given that a request from FDA

¹⁶Pub. L. No. 112-144, §1001, 126 Stat. at 1100 (codified at 21 U.S.C. § 356c(h)(2)).

means it has determined that there is a shortage of a life-sustaining drug that an increase in quota is necessary to address.

- Further, both agencies told us that they were subject to restrictions on exchanging the proprietary information they receive from drug manufacturers, which may be helpful to prevent or address shortages. At the time our report was issued in February 2015, the agencies had been working for more than 2 years to develop an updated memorandum of understanding (MOU) to share such information.

To address these barriers to effective coordination, we made three recommendations. First, we recommended that DEA and FDA promptly update the MOU between the two agencies. Second, we recommended that either in the MOU or a separate agreement, DEA and FDA specifically outline what information they will share and the time frames for sharing such information in response to a potential or existing drug shortage. Third, we recommended that DEA expeditiously establish formal policies and procedures to coordinate with FDA, as directed by FDASIA, with respect to expediting shortage-related quota applications. In commenting on a draft of our report, DEA did not explicitly agree or disagree with these three recommendations. The Department of Health and Human Services agreed with the two recommendations we made to FDA.

In March 2015, FDA and DEA updated the MOU to establish procedures regarding the exchange of proprietary and other sensitive information between DEA and FDA, which fully addresses one of our three recommendations. According to DEA, the two agencies have shared information under the auspices of the MOU at least six times in fiscal year 2016. Although the MOU established procedures for sharing information, it calls for the development of separate plans to specify precisely what information is to be shared, and who it is to be shared with. In October 2015, DEA said that it had met with FDA to determine the specific procedures by which information regarding drug shortages shall be exchanged, and a draft of such a work plan has been circulated between the two agencies for comment. As of June 2016, DEA expects the work plan to be completed no later than December 2016. DEA also noted that the work plan will contain formal policies and procedures to facilitate coordination with FDA, as directed by FDASIA. As a result, the two related recommendations remain open at this time.

DEA Has Provided More Information to Registrants about Their Controlled Substances Roles, but Additional Actions Are Needed to Fully Address Our Recommendations

In June 2015, we reported that DEA provided information to its registrants regarding their roles and responsibilities for preventing abuse and diversion through conferences, training, and other initiatives. We also found that DEA provided additional resources, such as manuals for specific registrant groups and DEA's Know Your Customer guidance for distributors. However, based on our generalizable survey of four DEA registrant groups, we reported that many registrants were not aware of these resources or they would like additional guidance, information, or communication from DEA to better understand their roles under the CSA.¹⁷ We recommended that DEA take three actions to address registrants' concerns. DEA has made some progress, but additional actions are needed to fully address our recommendations.

Many Registrants Were Not Aware of DEA Conferences and Other Resources

In June 2015, we reported that DEA periodically hosted events such as conferences or meetings for various components of its registrant population during which the agency provided information about registrants' CSA roles and responsibilities for preventing abuse and diversion. We found that DEA was also often a presenter at various conferences at the national, state, or local level, which registrants could attend. We asked distributors whether representatives of their facility attended DEA's 2013 Distributor Conference, and asked individual pharmacies and chain pharmacy corporate offices whether they or other representatives of their pharmacy (or pharmacy chain) had attended a Pharmacy Diversion Awareness Conference (PDAC).¹⁸ Based on our surveys, we estimated that 27 percent of distributors and 17 percent of individual pharmacies had participated in the DEA-hosted events, while 63 percent (20 of 32) of chain pharmacy corporate offices we surveyed

¹⁷GAO-15-471

¹⁸According to DEA, the purpose of the 2013 Distributor Conference was to provide an overview of federal laws and regulations that affect pharmaceutical and chemical distributors, such as recordkeeping, and suspicious orders reporting. DEA noted that PDACs are designed to assist pharmacy personnel in identifying and preventing diversion activity. Each 1-day conference is open to pharmacy personnel (pharmacists, pharmacy technicians, or loss prevention personnel) who are employed by pharmacies or hospitals/clinics that are registered with DEA in the state in which the conference is being conducted. As of October 2014, when our surveys closed, DEA had held 44 PDACs in 21 states since 2011.

had participated in a PDAC. Of the large percentages of distributors and pharmacies that did not participate in these conferences, many cited lack of awareness as the reason. For example, an estimated 76 percent of individual pharmacies that had not attended a PDAC and 35 percent of distributors that had not attended the 2013 Distributor Conference cited lack of awareness as a reason for not participating.¹⁹

Our June 2015 report also stated that DEA had created various resources, such as guidance manuals and a registration validation tool, which registrants could use to understand or meet their roles and responsibilities under the CSA. However, based on our surveys, we found that many registrants were not using these resources because they were not aware that they existed. For example, DEA had created guidance manuals for pharmacists and practitioners to help them understand how the CSA and its implementing regulations pertain to these registrants' professions. These documents were available on DEA's website. In 2011, DEA released guidance for distributors containing suggested questions a distributor should ask customers prior to shipping controlled substances (referred to as the Know Your Customer guidance). Additionally, DEA offered a registration validation tool on its website so that registrants, such as distributors and pharmacies, could determine if a pharmacy or practitioner had a valid, current DEA registration. However, our survey results suggested that many registrants were not using these resources that could help them better understand and meet their CSA roles and responsibilities because they were unfamiliar with them. For example, of particular concern were the estimated 53 percent of individual pharmacies that were not aware of either DEA's Pharmacist's Manual or the registration validation tool, and the 70 percent of practitioners that were not aware of DEA's Practitioner's Manual, and were therefore not using these resources.

The lack of awareness among registrants of DEA resources and conferences suggested that DEA may not have an adequate means of communicating with its registrant populations. Further, with so many registrants unaware of DEA's conferences and resources, we reported that DEA lacked assurance that registrants had sufficient information to

¹⁹According to DEA, every distributor was sent a notice of this conference by email, and for those emails that were rejected or returned, the agency attempted to contact the distributor via a different method.

understand and meet their CSA responsibilities. Therefore, we recommended that DEA identify and implement means of cost-effective, regular communication with distributor, pharmacy, and practitioner registrants, such as through listservs or web-based training. DEA agreed that communication from DEA to the registrant population was necessary and vital. As of April 2016, DEA reported that it had taken steps towards addressing this recommendation. In particular, DEA reported that it was in the process of developing web-based training modules for all of its registrant population, and was considering the best way to implement a listserv to disseminate information to its various registrant types. We plan to continue to monitor the agency's efforts in this area, and this recommendation remains open.

Distributors and Pharmacies Wanted Additional Information and Communication from DEA Regarding Their Roles in Preventing Abuse and Diversion

As we reported in June 2015, some responses to our registrant survey indicated that additional guidance for distributors regarding suspicious orders monitoring and reporting, as well as more regular communication, would be beneficial. In response to an open-ended question in our survey about how DEA could improve its Know Your Customer document, the guidance document DEA has provided to distributors, half of distributors (28 of 55) that offered comments said that they wanted more guidance from DEA. Additionally, just over one-third of distributors (28 of 77) reported that DEA's Know Your Customer document was slightly or not at all helpful.²⁰ Furthermore, in response to an open-ended question about what additional interactions they would find helpful to have with DEA, more than half of the distributors that offered comments (36 of 55) said that they needed more communication or information from, or interactions with, DEA. Some of the specific comments noted that distributors would like more proactive communication from DEA that was collaborative in nature, rather than being solely violation- or enforcement-oriented. Some of the additional communication and interactions proposed by distributors included quarterly meetings with the local field office and more training or conferences related to their regulatory roles and responsibilities.

Also, while DEA had created guidance manuals for pharmacists and practitioners, the agency had not developed a guidance manual or

²⁰Distributors were asked the question, "Based on your use of DEA's Know Your Customer guidance, how helpful is it for understanding your roles and responsibilities?"

comparable document for distributors. DEA officials told us that they believed the information in agency regulations was sufficient for distributors to understand their CSA responsibilities for suspicious orders monitoring and reporting. DEA officials also said that they met routinely with distributors and distributors had fewer requirements compared to other registrant types and officials did not believe such guidance was necessary. Additionally, DEA officials said that while distributors wanted specific instructions on how to avoid enforcement actions, DEA could not do that because circumstances that lead to enforcement actions (e.g., individual business practices) vary.

However, as we stated in our June 2015 report, a guidance document for distributors similar to the one offered for pharmacies and practitioners could help distributors further understand and meet their roles and responsibilities under the CSA for preventing diversion, though the document may not need to be as detailed. Specifically, we concluded that although DEA may not be able to provide guidance that will definitively answer the question of what constitutes a suspicious order or offer advice about which customers to ship to, DEA could, for example, provide guidance around best practices in developing suspicious orders monitoring systems. DEA could also enhance its proactive communication with distributors—which could be done, for example, via electronic means if additional in-person outreach would be cost prohibitive. Such steps are key to addressing distributors' concerns, because without sufficient guidance and communication from DEA, distributors may not be fully understanding or meeting their roles and responsibilities under the CSA for preventing diversion. Additionally, in the absence of clear guidance from DEA, our survey data showed that many distributors were setting thresholds on the amount of certain controlled substances that can be ordered by their customers (i.e., pharmacies and practitioners), which could negatively impact pharmacies and ultimately patients' access. For example, we estimated that 62 percent of individual pharmacies did business with distributors that put thresholds on the quantity of controlled substances they could order, and we estimated that 25 percent of individual pharmacies have had orders cancelled or suspended by distributors.

Responses to our surveys also showed that some pharmacies wanted updated or clearer guidance, as well as more communication and information, from DEA. For example, we found that DEA's Pharmacist's Manual was last updated in 2010, and since that time DEA had levied large civil fines against some pharmacies. Some pharmacy associations reported these fines had caused confusion in the industry about

pharmacists' CSA roles and responsibilities. In their responses to an open-ended question in our survey about DEA's Pharmacist's Manual, some chain pharmacy corporate offices (7 of 18) said that the manual needed updates or more detail, some chain pharmacy corporate offices (5 of 18) reported other concerns with the manual, and some individual pharmacies (13 of 33) said that the manual needed improvement, such as more specifics. For example, several chain pharmacy corporate offices commented that the manual needed to be updated to reflect changes in DEA enforcement practices or regulations (e.g., the rescheduling of hydrocodone from a schedule III to a schedule II drug).²¹

The need for clearer guidance for pharmacists was also suggested by some chain pharmacy corporate offices' responses to a question about DEA field office consistency. Specifically, when asked how consistent the responses of staff in different field offices had been to their inquiries about pharmacists' roles and responsibilities, nearly half of chain pharmacy corporate offices (8 of 19) that had contact with multiple DEA field offices said that staff responses were slightly or not at all consistent. In an open-ended response to this question, one chain pharmacy corporate office noted that in its interactions with different DEA field offices throughout the country it had received different, widely varying interpretations of DEA requirements that affected the chain's day-to-day operations, such as requirements for theft/loss reporting of controlled substances and requirements for prescribers to be reported when the prescriber fails to provide a written prescription. These responses from chain pharmacy corporate offices about field office inconsistencies suggested that the existing pharmacy guidance may not be clear even to some DEA field office officials.

Additionally, the desire for more or clearer guidance and more communication from DEA was a common theme in the responses offered from both individual pharmacies and chain pharmacy corporate offices to the open-ended questions in our survey related to DEA interactions. For example, in response to an open-ended question about what additional interactions they would find helpful to have with DEA headquarters or field office staff, nearly all of the chain pharmacy corporate offices that offered

²¹Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II, 79 Fed. Reg. 49661 (2014).

comments (15 of 18) said that they wanted more guidance or clearer interpretation of the guidance from DEA, more communication with DEA, or a more proactive, collaborative relationship with DEA. In addition, nearly a third of individual pharmacies (18 of 60) that offered open-ended answers to a question about any new guidance, resources, or tools that DEA should provide to help them understand their roles and responsibilities said that they would like more proactive communication from DEA through methods such as a newsletter or e-mail blast.

To help address the concerns raised by some distributor and pharmacy registrants, we recommended that DEA solicit input from distributors, or associations representing distributors, and develop additional guidance for distributors regarding their roles and responsibilities for suspicious orders monitoring and reporting. We also recommended that the office solicit input from pharmacists, or associations representing pharmacists, about updates and additions needed to existing guidance for pharmacists, and revise or issue guidance accordingly.

In commenting on our report, DEA raised concerns about the recommendation to solicit input from distributors and stated that short of providing arbitrary thresholds to distributors, it cannot provide more specific suspicious orders guidance because the variables that indicate a suspicious order differ among distributors and their customers. In April 2016, DEA provided information about ongoing efforts to educate distributors about their roles and responsibilities for monitoring and reporting suspicious orders, such as their Distributors' Conferences, and noted that it plans to host yearly training for distributors. However, DEA did not mention any plans to develop and distribute additional guidance for distributors. We continue to believe that a guidance document similar to the one offered for pharmacies and practitioners could help distributors further understand and meet their role and responsibilities under the CSA. Specifically, although DEA may not be able to provide guidance that will definitively answer the question of what constitutes a suspicious order or offer advice about which customers to ship to, DEA could, for example, provide guidance around best practices in developing suspicious orders monitoring systems. In the absence of clear guidance from DEA, our survey data show that many distributors are setting thresholds on the amount of certain controlled substances that can be ordered by their customers (i.e., pharmacies and practitioners), which can negatively impact pharmacies and ultimately patients' access. We plan to continue to monitor the agency's efforts in this area, and this recommendation remains open.

With respect to our recommendation that DEA solicit input from pharmacists, in commenting on our report, DEA described actions it would take to partially address the recommendation, including updating the Pharmacist's Manual to reflect two subject matter area changes related to the rescheduling of hydrocodone and new drug disposal regulations. However, at that time, DEA did not comment about providing any additional guidance to pharmacists related to their roles and responsibilities in preventing abuse and diversion under the CSA.

In April 2016, DEA reported that it continues to work with the National Association of Boards of Pharmacy regarding issues raised during stakeholder discussions, which resulted in a March 2015 consensus document published by stakeholders entitled "Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances."²² DEA also described other ways in which the agency works with pharmacists or associations representing pharmacists, such as during regional one-day Pharmacy Diversion Awareness Conferences, and noted that it was still working to update the Pharmacist's Manual regarding changes related to the rescheduling of hydrocodone and new drug disposal regulations. DEA also commented that it would continue to update or issue guidance as warranted, but again, did not indicate that it had updated, or planned to update, existing guidance to pharmacists related to their roles and responsibilities in preventing abuse and diversion under the CSA. We plan to continue to monitor the agency's efforts in this area, as well, and consequently this recommendation remains open.

²²The stakeholders who signed this consensus document included associations representing physicians, pharmacies, pharmacists, distributors, and boards of medicine and pharmacy.

DEA Agreed to Update Its Confidential Informants Policy to Be More Consistent with Attorney General Guidelines

In September 2015, we reported that DEA's confidential informants policy required agents to consider most of the factors identified in the Attorney General's Guidelines for conducting initial suitability reviews prior to using a person as an informant. Furthermore, in accordance with the Guidelines, DEA's policy required that a continuing suitability review be conducted at least annually. However, we determined that DEA's policy was either partially consistent with or did not address some provisions in the Guidelines regarding oversight of informants' authorized illegal activities. We recommended that DEA update its policy and corresponding monitoring processes to address these provisions from the Guidelines. As of June 2016, DEA had made progress, but had not fully implemented our recommendation.

In September 2015, we reported that DEA's policy was partially consistent with the Guidelines' requirements to provide written instructions to an informant regarding the parameters of the authorized otherwise illegal activity and to have the informant sign an acknowledgment of these instructions. Additionally, regarding the Guidelines' provisions on the suspension or revocation of authorization for an informant to engage in otherwise illegal activity, DEA's policy was consistent with the provision for revoking authorization in cases where DEA has reason to believe that an informant is not in compliance with the authorization. However, DEA's policy did not address circumstances unrelated to the informant's conduct in which DEA may, for legitimate reasons, be unable to comply with precautionary measures necessary for overseeing otherwise illegal activity. At the time of our review, DEA officials told us that they did not authorize informants to participate in otherwise illegal activity without agent supervision, and, therefore, these officials said they believe this requirement would not be applicable to DEA. However, we found that DEA's policy did not explicitly state that direct supervision of an agent is required for all instances of an informant's participation in otherwise illegal activity. Additionally, regardless of the circumstances for suspending or revoking an authorization for otherwise illegal activity, DEA's policy did not require the informant to sign a written acknowledgment that the authorization had been suspended or revoked.

As a result, we recommended that DEA, with assistance and oversight from the DOJ Criminal Division, update its policy and corresponding monitoring procedures to explicitly address the Guidelines' provisions on oversight of informants' illegal activities. DOJ concurred with this recommendation, and has coordinated with DEA on updating the agency's policy. According to an April 2016 memo, the Criminal Division

has reviewed a revised version of DEA's agents manual, which contains DEA's policies and practices regarding confidential informants, and the Criminal Division determined that the revised manual is fully consistent with the Guidelines. Based on follow up discussions with DOJ, as of June 2016, DEA's Office of the Chief Counsel was preparing the language needed to incorporate the new policy and expects to complete this process in summer 2016. At that time, we plan to review the updated policy to determine whether DEA has fully implemented our recommendation.

Chairman Grassley, Ranking Member Leahy, and Members of the Committee, this completes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

GAO Contacts and Staff Acknowledgments

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